

REMARKS

Status of the Claims

Claims 14, 15 and 17-21 are pending in this application. Claims 14, 15 and 17-21 stand rejected.

Withdrawn Rejections

Applicant appreciates the Examiner's indication that all of the previous rejections have been withdrawn.

Statement of Substance of Interview Under 37 C.F.R. § 1.133(b)

In accordance with 37 C.F.R. § 1.133(b) and M.P.E.P. § 713.04, Applicant provides a summary of the interview between Applicant's representatives and Examiners Landsman and Hissong conducted on March 26, 2008 ("the interview"). Applicant thanks the Examiners for agreeing to conduct the interview and appreciates the courtesies extended by the Examiners.

During the interview, Applicant's representatives explained that the specification teaches six working examples where patients treated in accordance with the claimed invention did not have unacceptable, severe side effects. *See* Examples 1-6. In particular, Applicant's representatives pointed out that in Example 2 "an excellent response was obtained" after treatment. Applicant's representatives also explained that Shachar et al., which discusses side effects from treatment with interferon- γ , does not specifically teach that unacceptable side effects are the result of intravenous administration. The Examiners appeared to preliminarily agree with Applicant's representatives, and indicated that a final determination would be communicated after receipt of this written response.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 14, 15 and 17-21 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement.

Applicant respectfully traverses this rejection.

The Office Action states that based on the teachings of Shachar et al. "one of ordinary skill in the art would predict that administration of the claimed dose range ... would also produce unacceptable, severe side effects." Office Action, page 5. The Office Action also states that "one of ordinary skill in the art would not predict that the claimed invention

could be practiced in a manner that would not result in the severe side effects known to be associated with administration of such doses, and would therefore require further, undue experimentation to practice the claimed method in a way that would minimize risks.”

Applicant respectfully disagrees.

As discussed during the interview, the specification teaches six working examples where patients treated in accordance with the claimed invention did not have unacceptable, severe side effects. *See* Examples 1-6. These results “show that IFN- γ was excellently effective against pemphigoid, an intractable disease, in all cases.” Specification, page 22, line 27 to page 23, line 1. Furthermore, the specification states that the invention “has made it possible to provide a method of treatment for pemphigoid for which there have been no fast-acting safe therapies.” *Id.* at page 23, lines 16-19. Accordingly, Applicants respectfully submit that one skilled in the art would understand that the claimed method could be practiced in a manner that would not result in the severe side effects alleged in the Office Action.

In view of the foregoing, Applicant respectfully requests withdrawal of the enablement rejection.

CONCLUSION


Applicant respectfully submits that claims 14, 15 and 17-21 are in condition for allowance, and such disposition is earnestly solicited. Should the Examiner believe that any issues remain after consideration of this response, the Examiner is encouraged to contact the Applicant's undersigned representative to discuss and resolve any such issues.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Date: March 28, 2008

By:



Robert M. Schulman
Registration No. 31,196

Alexander H. Spiegler
Registration No. 56,625

HUNTON & WILLIAMS LLP
Intellectual Property Department
1900 K Street, N.W., Suite 1200
Washington, D.C. 20006
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)
RMS/AHS:lm